

WSA Planning Meeting
October 6-10, 2003
DRAFT - FOR DISCUSSION PURPOSES ONLY

| | | | | | | | |
|--------|---|------------------|----------|--|--|--|--|
| N01352 | Investigating the Potential Applicability of Compromised Animal Models of Cigarette Smoke-Induced Emphysema | Vanscheeuwijk, P | Priority | | | | |
|--------|---|------------------|----------|--|--|--|--|

EVALUATION

EVALUATION FRAMEWORK

NON-CLINICAL (cont.)

| PROJECT NUMBER | PROJECT NAME | PROJECT LEADER | PRIORITY | Original Completion Date | Previous Completion Date | Revised Completion Date | COMMENTS |
|--------------------------|--|-----------------|----------|--------------------------|--------------------------|-------------------------|----------|
| CVD | | | | | | | |
| N01120 | CVD Biomarkers Evaluation | Schleef, R | Critical | | | | |
| N01357 | Method Development, CVD Biomarkers, Biochemistry | Kuhl, P | Critical | | | | |
| N01358 | Combined Smoke Inhalation and Feeding Study on Knockout Mouse Model of Atherosclerosis/Arteriothrombosis | Schleef, R | Critical | | | | |
| N01401 | Exercise Performance of Adults Smoking ACCORD or Conventional Cigarettes | Unverdorben, M. | Critical | 6/30/03 | 6/30/03 | 6/30/03 | Critical |
| N01402 | Influence of Smoking the EHCSS ACCORD® on Endothelium-Dependent Venoreactivity | Unverdorben, M. | Critical | (E) | | | |
| N01423 | Organ Bath Model System for CVD | Schleef, R | Critical | | | | |
| N01424 | Thrombosis Animal Model | Schleef, R | Critical | | | | |
| N01356 | Cardiac Telemetry Methods | Meurrens, K | Priority | | | | |
| N01359 | Joint Smoke Inhalation Pilot Study with German Heart Center and Other Groups | Von Holt, K | Priority | | | | |
| N01422 | Animal Models for Studying the Impact of Multiple Risk Factors on Cardiovascular Disease (CVD) | Schleef, R | Priority | | | | |
| N01360 | Proteomics of Serum to Identify Endpoints with Relevance for CVD | Schepers, G | Priority | | | | |
| N01188 | Flow cytometric assays for investigating cytotoxicity/apoptosis | Kindt, R | Priority | | | | |
| REPRO | | | | | | | |
| N01433 | Reduced Birth Weight Validation/MAO | Carmines, E | Priority | | | | |
| N01439 | In vitro Models for low birth weight | Carmines, E | Priority | | | | |
| DETERMINANTS OF EXPOSURE | | | | | | | |
| N01405 | Genomics/Proteomics Approaches - Differential Gene Expression | Davies, B | Critical | | | | |

1501 for 02 are G&R critical

1501 = 03/31/04 6/30/03 5/31/03

Red - Identified as Critical
Green - Kept as Critical
Blue - Priority or Secondary

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| CVD | | | | | | | |
| N01120 | CVD Biomarkers Evaluation | Schleef, R | Critical | | | | |
| N01357 | Method Development, CVD Biomarkers, Biochemistry | Kuhl, P | Critical | | | | |
| N01358 | Combined Smoke Inhalation and Feeding Study on Knockout Mouse Model of Atherosclerosis/Arteriothrombosis | Schleef, R | Critical | | | | |
| N01401 | Exercise Performance of Adults Smoking ACCORD or Conventional Cigarettes | Unverdorben, M. | Critical | 07/01/03 | 06/27/03 | 07/31/03 | |
| N01402 | Influence of Smoking the EHSS ACCORD® on Endothelium-Dependent Venoreactivity | Unverdorben, M. | Critical | | | | |
| N01423 | Organ Bath Model System for CVD | Schleef, R | Critical | | | | |
| N01424 | Thrombosis Animal Model | Schleef, R | Critical | | | | |
| N01356 | Cardiac Telemetry Methods | Meurrens, K | Priority | | | | |
| N01359 | Joint Smoke Inhalation Pilot Study with German Heart Center and Other Groups | Von Holt, K | Priority | | | | |
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| DETERMINANTS OF EXPOSURE | | | | | | | |
| N01405 | Genomics/Proteomics Approaches - Differential Gene Expression | Davies, B | Critical | | | | |

150 (+/-) were classified

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| CLINICAL | | | | | | | |
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| CANCER | | | | | | | |
| N01462 | Review of NCI database and other literature for functional genomics and/or proteomic studies characterizing early biomarkers for lung cancer | Sarkar, M. | Critical | | | | |
| COPD | | | | | | | |
| N01395 | Development of an Inflammation/Irritation Model for the Human Upper Respiratory Tract | Kobal, G | Critical <i>DVA</i> | 9/15/047 | | | |
| N01465 | Mucociliary Clearance (MCC) | Mendes, P. <i>M. G. 07</i> | Priority | | | | |
| N01487 | Biomarkers of inflammation in Bronchial Lavage fluid | Mendes, P. | Priority | | | | |
| CVD | | | | | | | |
| N01435 | Confirm the observation of endothelial dysfunction arising from acute ETS exposure; use results to develop a clinical assay to assess "reduced ETS" prototypes; and identify ETS components responsible for observed effects | Sanders, E | Critical | | | | |
| N01455 | Assessment of exercise performance of non/no-smokers exposed to ETS | Unverdorben, M. <i>Sander, T.</i> | Priority | | | | |
| N01466 | Early Biomarkers of Inflammation | Unverdorben, M. | Priority <i>Unverdorben</i> | | | | |
| N01489 | Influence of Smoking PREPs on Left Ventricular Diastolic Function | Unverdorben, M. | Priority | | | | |
| N01490 | Influence of Smoking versus No-smoking on Intima-Media-Thickness | Unverdorben, M. | Priority | | | | |
| DETERMINANTS OF EXPOSURE | | | | | | | |
| N01457 | Method Development for Retention Study | Nelson, B | Critical | 9/15/2004 | | | |

*Accord
JLI Long Term W75 mg
studies*

Nov 2008

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| GENERAL | Clinical Study Guidelines | | Critical | | | | |
| N01459 | TES Follow-up Study | Oey, J | Critical | | | | |
| N01458 | Method development for retention study | Feng, S. | Critical | 12/31/03 | 12/31/03 | 12/31/03 | |
| N01470 | Longitudinal Clinical Risk Evaluation Study | Roethig, H | Critical | | | | NEED UPDATED PROJECT SHEET |
| N01491 | Marlboro Short Term Full Flavor Exposure | Gagava, M Mendes, P | Critical | | | | |
| N01492 | Marlboro Full Flavor Long Term | Gagava, M Mendes, P | Critical | | | | |
| N01460 | Characterization of enzyme induction as an early biomarker of potential harm | Sarkar, M. | Priority | | | | |
| N01456 | Non-linear modeling of biomarkers from the Multi-Center Total Exposure Study | Nelson, B | Priority | | | | |
| N01467 | Statistical data mining to provide alternative clinical trial designs for PREP Evaluation | Liang, Q. | Priority | | | | |
| N01468 | Statistical approaches for developing overall exposure reduction scores | Liang, Q. | Priority | | | | |
| N01488 | Bronchial hyperresponsiveness | Mendes, P. | Priority | | | | |
| N01104 | Haemoglobin Adducts of Aromatic Amines (AA) | Schorp, M | Secondary | | | | |

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7487

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Source: <https://www.industrydocuments.ucsf.edu/docs/rnlj0001>